

WHAT IS CLAIMED IS:

1. A method of diagnosing a cancer in an individual, comprising the steps of:

5 (a) obtaining a biological sample from said individual; and

(b) detecting stratum corneum chymotrypsin enzyme in said sample, wherein the presence of stratum corneum chymotrytic enzyme in said sample is indicative of the presence of a cancer in said individual, wherein the absence of stratum corneum chymotrytic enzyme in said sample is indicative of the absence of a cancer in said individual.

15 2. The method of claim 1, wherein said biological sample is selected from the group consisting of blood, urine, saliva, tears, interstitial fluid, ascites fluid, tumor tissue biopsy and circulating tumor cells.

20 3. The method of claim 1, wherein said detection of said stratum corneum chymotrytic enzyme is by means selected

from the group consisting of Northern blot, Western blot, PCR, dot blot, ELIZA sandwich assay, radioimmunoassay, DNA array chips and flow cytometry.

5           4. The method of claim 1, wherein said cancer is selected from the group consisting of ovarian, breast, lung, colon, prostate and others in which stratum corneum chymotrytic enzyme is overexpressed.

10           5. A method for detecting malignant hyperplasia in a biological sample, comprising the steps of:

(a) isolating mRNA from said sample; and

15           (b) detecting stratum corneum chymotrytic enzyme mRNA in said sample, wherein the presence of said stratum corneum chymotrytic enzyme mRNA in said sample is indicative of the presence of malignant hyperplasia, wherein the absence of said stratum corneum chymotrytic enzyme mRNA in said sample is indicative of the absence of malignant hyperplasia.

20           6. The method of claim 5, further comprising the step

of:

comparing said stratum corneum chymotrytic enzyme mRNA to reference information, wherein said comparison provides a diagnosis of said malignant hyperplasia.

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7. The method of claim 5, further comprising the step of:

comparing said stratum corneum chymotrytic enzyme mRNA to reference information, wherein said comparison determines a treatment of said malignant hyperplasia.

8. The method of claim 5, wherein said detection of said stratum corneum chymotrytic enzyme mRNA is by PCR amplification.

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9. The method of claim 8, wherein said PCR amplification uses primers selected from the group consisting of SEQ ID No. 10 and SEQ ID No. 11.

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10. The method of claim 5, wherein said biological

sample is selected from the group consisting of blood, urine, saliva, tears, interstitial fluid, ascites fluid, tumor tissue biopsy and circulating tumor cells.

5 11. A method for detecting malignant hyperplasia in a biological sample, comprising the steps of:

(a) isolating protein from said sample; and

10 (b) detecting stratum corneum chymotrytic enzyme protein in said sample, wherein the presence of said stratum corneum chymotrytic enzyme protein in said sample is indicative of the presence of malignant hyperplasia, wherein the absence of said stratum corneum chymotrytic enzyme protein in said sample is indicative of the absence of malignant hyperplasia.

15 12. The method of claim 11, further comprising the step of:

comparing said stratum corneum chymotrytic enzyme protein to reference information, wherein said comparison provides a diagnosis of said malignant hyperplasia.

13. The method of claim 11, further comprising the step of:

comparing said stratum corneum chymotryptic enzyme protein to reference information, wherein said comparison  
5 determines a treatment of said malignant hyperplasia.

14. The method of claim 11, wherein said detection is by immunoaffinity to an antibody, wherein said antibody is specific for stratum corneum chymotryptic enzyme.

15. The method of claim 11, wherein said biological sample is selected from the group consisting of blood, urine, saliva, tears, interstitial fluid, ascites fluid, tumor tissue biopsy and circulating tumor cells.

16. A method of inhibiting expression of endogenous stratum corneum chymotryptic enzyme in a cell, comprising the step of:

introducing a vector into a cell, wherein said vector  
20 comprises a stratum corneum chymotryptic enzyme gene in opposite

orientation operably linked to elements necessary for expression,  
wherein expression of said vector in said cell produces stratum  
corneum chymotrytic enzyme antisense mRNA, wherein said stratum  
corneum chymotrytic enzyme antisense mRNA hybridizes to  
5 endogenous stratum corneum chymotrytic enzyme mRNA, thereby  
inhibiting expression of endogenous stratum corneum chymotrytic  
enzyme in said cell.

17. A method of inhibiting stratum corneum  
10 chymotrytic enzyme protein in a cell, comprising the step of:

introducing an antibody into a cell, wherein said antibody  
is specific for a stratum corneum chymotrytic enzyme protein or a  
fragment thereof, wherein binding of said antibody to said stratum  
corneum chymotrytic enzyme protein inhibits said stratum corneum  
15 chymotrytic enzyme protein.

18. A method of targeted therapy to an individual,  
comprising the step of:

administering a compound to an individual, wherein said  
20 compound has a targeting moiety and a therapeutic moiety, wherein

said targeting moiety is specific for stratum corneum chymotrytic enzyme.

19. The method of claim 18, wherein said targeting  
5 moiety is selected from the group consisting of an antibody specific for stratum corneum chymotrytic enzyme and a ligand or ligand binding domain that binds stratum corneum chymotrytic enzyme.

20. The method of claim 18, wherein said therapeutic  
10 moiety is selected from the group consisting of a radioisotope, a toxin, a chemotherapeutic agent, an immune stimulant and a cytotoxic agent.

21. The method of claim 18, wherein said individual  
15 suffers from a disease selected from the group consisting of ovarian cancer, lung cancer, prostate cancer, colon cancer and other cancers in which stratum corneum chymotrytic enzyme is overexpressed.

22. A method of vaccinating an individual against  
20 stratum corneum chymotrytic enzyme, comprising the step of:

inoculating an individual with a stratum corneum  
chymotrytic enzyme protein or fragment thereof, wherein said  
stratum corneum chymotrytic enzyme protein or fragment thereof  
lack stratum corneum chymotrytic enzyme protease activity,  
5 wherein said inoculation with said stratum corneum chymotrytic  
enzyme protein or fragment thereof elicits an immune response in  
said individual, thereby vaccinating said individual against stratum  
corneum chymotrytic enzyme.

10 23. The method of claim 22, wherein said individual  
has a cancer, is suspected of having a cancer or is at risk of getting a  
cancer.

24. The method of claim 22, wherein said stratum  
15 corneum chymotrytic enzyme fragment is selected from the group  
consisting of a 9-residue fragment up to a 20-residue fragment.

25. The method of claim 24, wherein said 9-residue  
fragment is selected from the group consisting of SEQ ID Nos. 31, 32,  
20 33, 34, 35, 36, 80, 86 and 99.



26. A method of producing immune-activated cells directed toward stratum corneum chymotrytic enzyme, comprising the steps of:

exposing dendritic cells to a stratum corneum chymotrytic enzyme protein or fragment thereof, wherein said stratum corneum chymotrytic enzyme protein or fragment thereof lacks stratum corneum chymotrytic enzyme protease activity, wherein said exposure to said stratum corneum chymotrytic enzyme protein or fragment thereof activates said dendritic cells, thereby producing immune-activated cells directed toward stratum corneum chymotrytic enzyme.

27. The method of claim 26, wherein said immune-activated cells are selected from the group consisting of B-cells, T-cells and dendrites.

28. The method of claim 26, wherein said stratum corneum chymotrytic enzyme fragment is selected from the group consisting of a 9-residue fragment up to a 20-residue fragment.

29. The method of claim 28, wherein said 9-residue fragment is selected from the group consisting of SEQ ID Nos. 31, 32, 33, 34, 35, 36, 80, 86 and 99.

5 30. The method of claim 26, wherein said dendritic cells are isolated from an individual prior to said exposure, wherein said activated dendritic cells are reintroduced into said individual subsequent to said exposure.

10 31. The method of claim 30, wherein said individual has a cancer, is suspected of having a cancer or is at risk of getting a cancer.

15 32. An immunogenic composition, comprising an immunogenic fragment of a stratum corneum chymotryptic enzyme protein and an appropriate adjuvant.

20 33. The immunogenic composition of claim 32, wherein said stratum corneum chymotryptic enzyme fragment is selected from the group consisting of a 9-residue fragment up to a 20-residue

fragment.

34. The immunogenic composition of claim 33, wherein  
said 9-residue fragment is selected from the group consisting of SEQ  
5 ID Nos. 31, 32, 33, 34, 35, 36, 80, 86 and 99.

35. An oligonucleotide having a sequence  
complementary to SEQ ID No. 30.

36. A composition comprising the oligonucleotide of  
claim 35 and a physiologically acceptable carrier.

37. A method of treating a neoplastic state in an  
individual in need of such treatment, comprising the step of:

15 administering to said individual an effective dose of the  
oligonucleotide of claim 35.

38. The method of claim 37, wherein said neoplastic  
state is selected from the group consisting of ovarian cancer, breast  
20 cancer, lung cancer, colon cancer, prostate cancer and other cancers

in which stratum corneum chymotrytic enzyme is overexpressed.

39. A method of screening for compounds that inhibit stratum corneum chymotrytic enzyme activity, comprising the steps

5 of:

contacting a sample with a compound, wherein said sample comprises stratum corneum chymotrytic enzyme protein; and

assaying for stratum corneum chymotrytic enzyme protease activity, wherein a decrease in said stratum corneum chymotrytic enzyme protease activity in the presence of said compound relative to stratum corneum chymotrytic enzyme protease activity in the absence of said compound indicatives the compound inhibits stratum corneum chymotrytic enzyme activity.